Complete Summary

GUIDELINE TITLE

Procedure guideline for lymphoscintigraphy and the use of intraoperative gamma probe for sentinel lymph node localization in melanoma of intermediate thickness.

BIBLIOGRAPHIC SOURCE(S)

Alazraki N, Glass EC, Castronovo F, Valdes Olmos RA, Podoloff D. Procedure guideline for lymphoscintigraphy and the use of intraoperative gamma probe for sentinel lymph node localization in melanoma of intermediate thickness, 1.0. Reston (VA): Society of Nuclear Medicine; 2002 Jun 15. 6 p. [18 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Intermediate stage primary melanoma (Breslow 0.76 to 4.0 mm)

GUIDELINE CATEGORY

Diagnosis
Evaluation

CLINICAL SPECIALTY

Nuclear Medicine
Oncology
Radiology

INTENDED USERS

Allied Health Personnel
Physicians

GUIDELINE OBJECTIVE(S)

To assist nuclear medicine practitioners in recommending, performing, interpreting, and reporting the results of (1) lymphoscintigraphy for identifying sentinel lymph nodes for excisional biopsy in patients with melanoma, and (2) the use of intraoperative gamma probe in the operating room

TARGET POPULATION

Patients with intermediate stage primary melanoma (Breslow 0.76 to 4.00 mm) with no clinical evidence of nodal involvement or distant tumor spread

Note: Exclusions may include patients with extensive previous surgery in the region of the primary tumor site or targeted lymph node bed and patients with known metastases.

INTERVENTIONS AND PRACTICES CONSIDERED

1. Lymphoscintigraphy
2. Intraoperative gamma probe

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature searches were performed. In addition, references known to experts and references from the nuclear medicine community were considered.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Drafts of the guideline were submitted to members of the Guideline Development subcommittee (methodologists) and the Task Force (subject experts). These reviewers indicated on a line-by-line basis any suggestions or recommendations for the revision of the guideline. The percentage of agreement for all reviewers was calculated for each revision and compiled by the Society of Nuclear Medicine (SNM) central office. It is expected that the percentage of agreement will increase with each revision.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

When the Task Force and Guideline Development Subcommittee completed their edits, draft procedure guidelines were distributed to the Society of Nuclear Medicine (SNM) Sample Review Group for comment. (The SNM Sample Review

Group is a cross-section of approximately 100 nuclear medicine practitioners representing every field of specialization).

The guideline was approved June 15th, 2002 by the SNM Commission on Health Care Policy, the Board of Directors, and the House of Delegates.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Background Information and Definitions

A. This guideline is written specifically for lymphoscintigraphy in patients with primary melanomas that originate in the skin. Staging of these tumors is based on tumor thickness (Breslow measurement) and level of skin invasion (Clark's level), both of which are determined by the pathologist from a biopsy sample. Ample data correlate patient survival with Breslow and Clark measurements.

   In the past, elective lymph node dissection (ELND) of the lymphatic bed believed most likely to drain the primary tumor site (based on Sappey's classic anatomic description of cutaneous lymphatic flow) was used as part of the staging procedure for melanoma. ELND has been a controversial staging procedure for patients with intermediate (I and II) stage melanoma, because approximately 80% have tumor-negative lymph nodes and therefore do not need ELND, a procedure associated with significant morbidity and cost. The sentinel lymph node excisional biopsy procedure, in contrast, is simpler and not associated with significant morbidity, provides accurate information about lymphatic drainage patterns, and allows the surgeon to make a smaller incision directly over the node, based on the image and probe counts.

   Lymphoscintigraphy images readily demonstrate the unpredictability of lymphatic drainage patterns. Sentinel lymph node biopsy, after identification by lymphoscintigraphy and excision using the intraoperative gamma probe and/or blue dye technique, is frequently performed in patients without either clinically apparent metastases or early intermediate-stage melanoma (Clark level <4; Breslow thickness 0.76 to 4 mm) because of its significant diagnostic and prognostic information.

B. Definitions
   1. Lymphoscintigraphy: Imaging pathways of lymphatic flow and lymph nodes after injection of a radiopharmaceutical that is absorbed by the lymphatics.
   2. Sentinel lymph node: The first lymph node in a lymph node bed to receive lymphatic drainage from a tumor. Often drainage to more than 1 lymph node group and sentinel node is identified.
   3. Blue dye technique: Intraoperative injection (usually peritumoral) of isosulfan blue dye for the purpose of staining lymphatic vessels and sentinel lymph nodes so that they can be identified visually during surgery for excisional biopsy.

4. Gamma-detecting intraoperative probe: Small, hand-held radiation-detecting device that uses auditory signals and meter read-outs of counts detected. The intraoperative gamma probe can be used effectively by the surgeon and nuclear medicine physician as a guide to find the radiolabeled sentinel lymph node(s).

Common Indications

A. Sentinel node localization and excision using radionuclide methods are performed in the care of patients with:
    1. Intermediate stage primary melanoma (Breslow 0.76 to 4.0 mm)
    2. No clinical evidence of nodal involvement
    3. No clinical evidence of distant tumor spread
B. Exclusions may include patients with:

    1. Extensive previous surgery in the region of the primary tumor site or targeted lymph node bed
    2. Patients with known metastases

Procedure

The detailed procedure recommendations in the guideline address the following areas: patient preparation; information pertinent to performing the procedure (i.e., important data that the physician should have about the patient at the time the exam is performed and interpreted); precautions; information regarding the radiopharmaceutical (i.e., ranges of administered activity, organ receiving the largest radiation dose, effective dose); image acquisition; interventions; processing; interpretation/reporting; quality assurance; and sources of error.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of lymphoscintigraphy and intraoperative gamma probe for sentinel lymph node localization in melanoma of intermediate thickness

POTENTIAL HARMS

Radiation safety issues arise for operating room personnel, pathology personnel, and nuclear medicine personnel. Nurses, physicians, and technologists involved

with patients who undergo lymphoscintigraphy and intraoperative probe sentinel node localization studies are instructed to wear radiation badges according to each institution's policy. Actual exposures from the activity levels used for these procedures are sufficiently low that badging is not essential for individuals who are not involved in other radiation procedures. The decision to badge personnel whose only radiation involvement is with sentinel node studies lies with the local institution. The following information is useful in making this determination.

A. The administered radioactivity is <18.5 MBq (500 microcurie), of which approximately 1%, 185 kBq (5 microcurie), might migrate to a sentinel lymph node.
B. The radiation dose to the hands of the surgeon has been estimated to be 5 to 94 microsievert (0.5 to 9.0 mrem) per patient. Relative to the radiation doses humans receive in 1 year from cosmic and natural background sources (about 3 mSv [300 mrem] effective whole body dose), a surgeon could perform roughly 30 to 60 melanoma sentinel node surgeries in a year and not receive as much finger radiation exposure as that received by the whole body from the natural environmental.
C. Radiation doses to pathology personnel who handle the radioactive sentinel node and primary tumor specimen (including the injection site) for a limited period would be no greater than that received by the surgeon. Therefore, the histological specimen can be processed without delay, and patient care is not compromised.
D. Radioactive waste from the operating room (sponges, etc.) and pathology should be collected according to institutional radiation safety procedures. This waste will also be a biohazard and should be handled accordingly.

CONTRAINDICATIONS

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Exclusions may include patients with extensive previous surgery in the region of the primary tumor site or targeted lymph node bed and patients with known metastases.

QUALIFYING STATEMENTS

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- The Society of Nuclear Medicine has written and approved guidelines to promote the cost-effective use of high quality nuclear medicine procedures. These generic recommendations cannot be applied to all patients in all practice settings. The guidelines should not be deemed inclusive of all proper procedures or exclusive of other procedures reasonably directed to obtaining the same results. The spectrum of patients seen in a specialized practice setting may be quite different than the spectrum of patients seen in a more general practice setting. The appropriateness of a procedure will depend in part on the prevalence of disease in the patient population. In addition, the resources available to care for patients may vary greatly from one medical facility to another. For these reasons, guidelines cannot be rigidly applied.

- Advances in medicine occur at a rapid rate. The date of a guideline should always be considered in determining its current applicability.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Alazraki N, Glass EC, Castronovo F, Valdes Olmos RA, Podoloff D. Procedure guideline for lymphoscintigraphy and the use of intraoperative gamma probe for sentinel lymph node localization in melanoma of intermediate thickness, 1.0. Reston (VA): Society of Nuclear Medicine; 2002 Jun 15. 6 p. [18 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Jun 15

GUIDELINE DEVELOPER(S)

Society of Nuclear Medicine, Inc - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of Nuclear Medicine (SNM)

GUIDELINE COMMITTEE

Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Society of Nuclear Medicine (SNM) Web site.

Print copies: Available from SNM, Division of Health Care Policy, 1850 Samuel Morse Dr, Reston, VA 20190-5316; Phone: 1-800-513-6853 or 1-703-326-1186; Fax: 703-708-9015; E-Mail: ServiceCenter@snm.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Society of Nuclear Medicine. Procedure guideline for guideline development. Reston (VA): Society of Nuclear Medicine; 2001 Jun (version 3.0). Electronic copies: Available from the Society of Nuclear Medicine Web site.
- Society of Nuclear Medicine. Performance and responsibility guidelines for NMT. Reston (VA): Society of Nuclear Medicine; 2003. Electronic copies: Available from the Society of Nuclear Medicine Web site.

Print copies: Available from SNM, Division of Health Care Policy, 1850 Samuel Morse Dr, Reston, VA 20190-5316; Phone: 1-800-513-6853 or 1-703-326-1186; Fax: 703-708-9015; E-Mail: ServiceCenter@snm.org.

PATIENT RESOURCES

None available

NGC STATUS

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